



**RFE MEMO**

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**Product Description(s):** V-PLEX® and V-PLEX Plus Human Insulin Kit

**Catalog Number(s) / Size(s):** K151S5-Series

**Lot Number:** K0082104

Based on additional testing, the original date of expiration for this kit has been extended by 20 months. The expiration date of K0082104 has been extended to 31 OCT 2023.

The expiration dates for the following kit components have also been extended:

Description	Lot Number	Original Expiration Date	New Expiration Date
Human Insulin Plate	Z0047169	28 FEB 2022	31 OCT 2023
Human Insulin Antibody	D0081371	31 MAR 2023	31 OCT 2023

Function	Name	Signature	Date
Quality	Karen Hamilla		25 OCT 2022

This memo supersedes all other statements regarding date of expiration for this product.

## CERTIFICATE OF ANALYSIS

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**Product Description:** V-PLEX® and V-PLEX Plus Human Insulin Kit

**Kit Lot Number:** K0082104

**Expiration Date:** 28 Feb 2022

**Kit Catalog Numbers:** K151S5-Series

**Precision and Accuracy Specifications:**

		Calibrator		Metabolic Panel 1 Control 1		Metabolic Panel 1 Control 2		Metabolic Panel 1 Control 3	
Spot	Name	Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	Insulin	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%

		LLOQ			ULOQ		
Spot	Name	Value	Recovery	CV	Value	Recovery	CV
1	Insulin	0.0700	80% - 120%	< 20%	19.5	80% - 120%	< 20%

**Stock Concentration of Calibrator:**


Spot	Name	Conc.	Units
1	Insulin	30.6	µIU/mL

**Lot-Specific Components:**

Description	Lot Number	Storage Temperature	Expiration Date
Human Insulin Plate	Z0047169	2-8°C	28 Feb 2022
Human Insulin Antibody	D0081371	2-8°C	31 Mar 2023
Metabolic Panel 1 Calibrator Blend	A0080230	2-8°C	30 Sep 2024
Diluent 11	M0110056	≤ -10°C	31 Oct 2024
Diluent 56	M0560004	≤ -10°C	31 Jan 2025

Additional components may be provided to execute the assay. Additional components are not lot-specific.

The above product is intended for Research Use Only. Not for use in Diagnostic Procedures.

	Name	Function	Signature	Date
Review/Approval	Karen Hamilla	Quality		25 OCT 2022